

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

**S-METHOPRENE
(B2E-09)**

STUDY TYPE: Waiver Requests for Acute Mammalian Toxicity Data

MRID 46763209

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

Prepared by
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Task Order No. 05-059

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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DATA EVALUATION RECORD

EPA Secondary Reviewer: *Angela Gonzalez*

STUDY TYPE: Waiver Requests for Mammalian Toxicity Data

MRID NO: 46763209

DP BARCODE: DP327777

CASE NO: Not provided

SUBMISSION NO: Not provided

TEST MATERIAL: B2E-09 (a.i., 2.5% w/w S-methoprene)

STUDY NO: Not provided

SPONSOR: B2E Biotech LLC, 2228 Montauk Highway,
Bridgehampton, NY 11932-1483

TESTING FACILITY: N/A

TITLE OF REPORT: Response to Tier I Biochemical Pesticide Data
Requirements for B2E-09

AUTHOR: Mileson, B.E.

STUDY COMPLETED: January 31, 2006

**CONFIDENTIALITY
CLAIMS:** None

**GOOD LABORATORY
PRACTICE:** A signed GLP statement was provided. The study is not
GLP compliant. No quality assurance unit was in place,
and no study director was assigned

CONCLUSION: Toxicity category III. The information provided is
inadequate to support toxicity category IV due to lack of
quantitative data for dermal and eye irritation and dermal
sensitization data requirements. The discussion of eye,
skin and inhalation exposure to dust from the EP was not
adequately addressed. [REDACTED]

ACCEPTABLE, pending submission of requested
information and adequate label revisions.

Test Material

B2E-09 (a.i., 2.5% w/w S-methoprene)

Product Description

B2E-09 is an end use product formulated as a briquet to control mosquitoes. B2E-09 is intended for use in pastures, meadows, and a variety of standing waters, including marshes, ponds, basins, drains, and ditches. As the briquet dissolves in water, it continuously releases the insect growth regulator S-methoprene to prevent mosquito development. Treated larvae develop normally to the pupal stage, where they die.

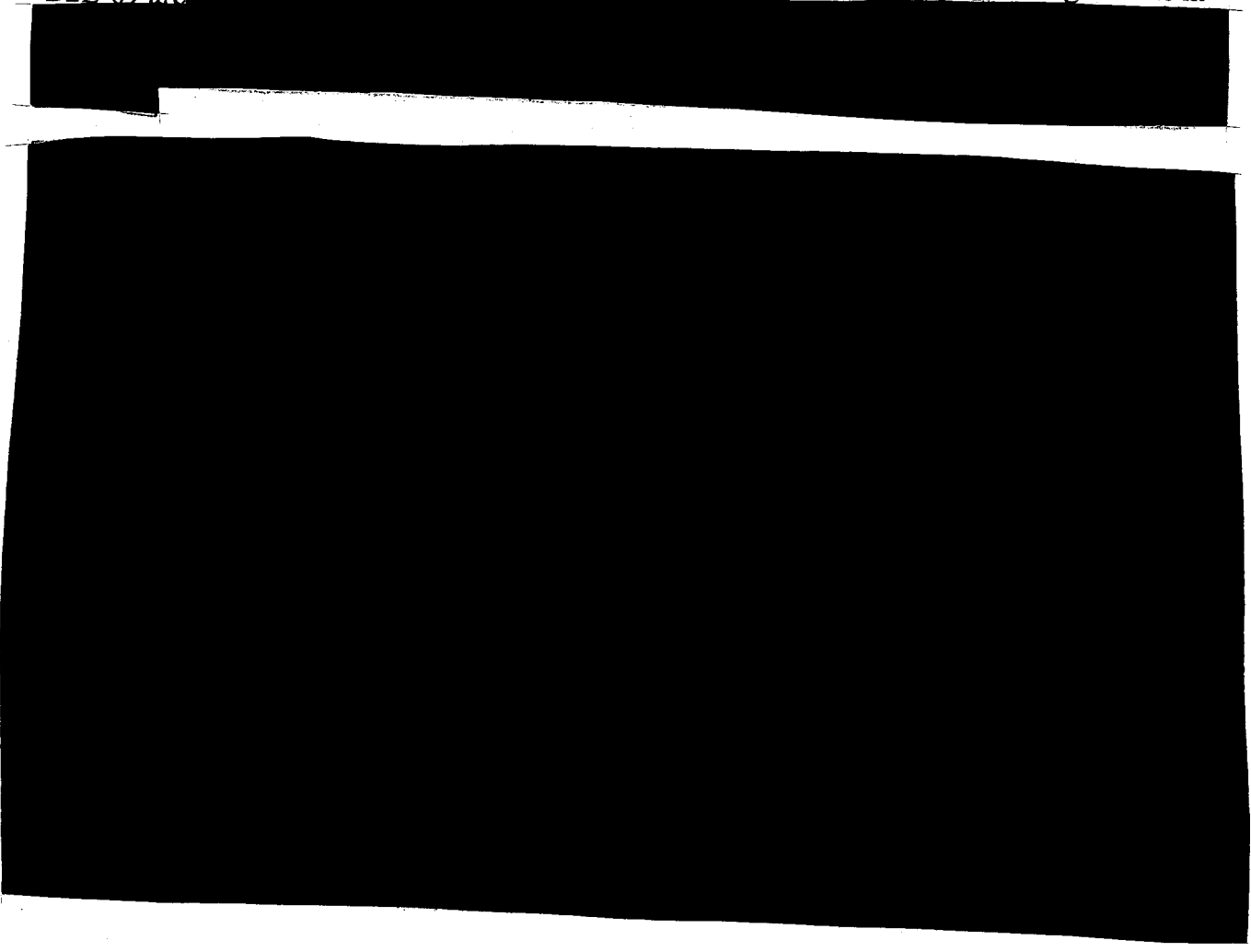
Waiver Requests

The registrant is requesting waivers for the following data requirements:

Acute Oral Toxicity	OPPTS 870-1100
Acute Dermal Toxicity	OPPTS 870.1200
Acute Inhalation Toxicity	OPPTS 870.1300
Acute Eye Irritation	OPPTS 870.2400
Primary Dermal Irritation	OPPTS 870.2500
Dermal Sensitization	OPPTS 870.2600

Rationale

The active ingredient in B2E-09 is technical grade S-methoprene (2.5%). The inert ingredients in B2E-09 are



INERT INGREDIENT INFORMATION IS NOT INCLUDED

In an acute oral toxicity study using the TGAI, S-methoprene (95.5%) was not toxic to rats receiving the limit dose of 5000 mg/kg (MRID 45087309), and gross necropsy was unremarkable.

In an acute dermal toxicity study using the TGAI, S-methoprene (95.5%) was not toxic to rabbits receiving the limit dose of 5000 mg/kg (MRID 45087310), and gross necropsy was unremarkable.

In an acute inhalation toxicity study using the TGAI, S-methoprene (95.5%) was not toxic to rats receiving the limit dose of 2.10 mg/L for four hours (MRID 45087311). Clinical signs included nasal discharge, irregular respiration, and hypoactivity, all of which resolved within three days. Gross necropsy at the end of the 14-day observation period was unremarkable. Per the registrant, B2E-09 is formulated as a briquet coated with [REDACTED] so inhalation exposure is unlikely. The discussion of the possibility of inhalation exposure to [REDACTED] to the applicator was not adequately discussed.

In a primary eye irritation study using the TGAI, S-methoprene (95.5%) was minimally irritating to the eyes of rabbits, producing only conjunctivitis immediately after instillation (MRID 45087312). The incidence and severity of irritation decreased thereafter, with resolution in all animals within 48 hours. Per the registrant, B2E-09 is formulated as a briquet coated with [REDACTED] so ocular exposure is unlikely. The discussion of the possibility of eye exposure to [REDACTED] to the applicator was not adequately discussed.

In a primary skin irritation study using the TGAI, S-methoprene (95.5%) was slightly irritating to rabbits receiving a topical dermal dose of 0.5 mL for four hours (MRID 45087313). Very slight erythema and very slight to well-defined edema were observed one hour post-exposure, with resolution within 24 hours. [REDACTED] can be a skin irritant, but since it is present at less than [REDACTED] by weight of B2E-09, is not expected to contribute significantly to any potential dermal irritation by the product. Per the registrant, B2E-09 is formulated as a briquet coated with [REDACTED] therefore potential dermal exposure would be minimized. Because the EP contains dermal irritants such as [REDACTED] and the rationale provided to waive the dermal irritation study requirement did not provide quantitative toxicological data, the current label language is inadequate.

In a dermal sensitization study using the TGAI, S-methoprene (95.5%) was not a contact sensitizer to guinea pigs (Buehler method, MRID 45087314). No signs of irritation of reactivity were observed in the animals. Per the registrant's rationale, [REDACTED] may be a sensitizer to some people, but since it is present at less than [REDACTED] by weight of B2E-09, is not expected to contribute significantly to any potential sensitization by the product. The amount of [REDACTED] present in [REDACTED] and in the [REDACTED] together is less than [REDACTED] of the B2E-09 formulation, making it unlikely to contribute to any potential sensitization by the product (per the registrant). B2E-09 is formulated as a briquet coated with [REDACTED]. Due to the lack of quantitative data on the ingredients that may be sensitizers, it cannot be concluded that there is no likelihood that the EP could be a dermal sensitizer.